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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/722,256
Filing Date: November 25, 2003
Appellant(s): CARNEY ET AL.

Sheng-Hsin Hu
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/20/2008 appealing from the Office action mailed 4/10/2008.

For the record, Appellant's sequence is not in compliance with the requirements of 37 CFR 1.821-1.825. The application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c). Nor does it contain a copy of the "Sequence Listing" in computer readable form as required by 37 CFR 1.821(e). However, the issue of compliance will be held in abeyance until a decision has been rendered by the Board of Patent Appeals and Interferences.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the appellant patent owner brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claim 3 remains rejected under 35 USC 103(a) as being unpatentable over Winterton et al, Sakuma et al., as applied to claim 1, and in further view of Diaz-Achirica et al. Claim 16 remains rejected under 35 USC 103(a) as being unpatentable over Winterton et al, Sakuma et al., and Okrongly, as applied to claim 1, and further in view of Diaz-Achirica et al.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,213,801	Sakuma et al.	5-1993
US 4,933,410	Okrongly	5-1990
US 2001/0045676	Winterton et al.	11-2001

Diaz-Achirica et al., "Permiabilization of the mitochondrial inner membrane by short cecropin-A-melittin hybrid peptides." European Journal of Biochemistry 1994:224;257-263.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1) Claim 1 is rejected under 35 USC 103(a) as being unpatentable over Winterton et al, (US 2001/0045676) in view of Sakuma et al., (US 5,231,801).

Winterton et al. teach a method of forming a contact lens within a mold with polyionic materials such as polyanionic and polycationic materials. (See Abstract and [0012].) The method involves application of oppositely charged polyionic materials creating a bilayer, which is essentially not covalently bonded to the contact lens. The reference teaches various other materials may be added such as antimicrobials and antibacterials (See pg. 2, [0019].)

Winterton et al. does not teach where the contact lens is a silicone hydrogel.

Sakuma et al. teach contact lenses are commonly made using a silicone containing hydrogel. The reference teaches a contact lens material that prevents breeding of bacteria to protect the cornea (see col. 1, lines 37-39).

The combination of Winterton and Sakuma teach the claimed invention in regard to 1(b).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to have used a silicone hydrogel contact lens as the contact lens in the method of Winterton, since contact lenses are commonly made using silicone hydrogel, as evidenced by Sakuma.

2) Claim 1 is rejected under 35 USC 103(a) as being unpatentable over Winterton et al., and Sakuma et al., and in further view of Okrongly (US 4,933,410).

Winterton et al., and Sakuma et al., taught above, do not teach that antimicrobial peptides are covalently attached to the LbL coating through the reactive sites.

Okrongly teaches covalent attachment of macromolecules on substrate surfaces. The reference teaches that substantially un-crossliked polystyrene products are functionalized employing hydroxymethylamides for electrophilic substitution of the phenyl groups. The resulting polystyrene may be used for reacting with a wide variety of functionalities, particularly associated with macromolecules; to provide for a high density of covalently bonded macromolecules (see column 2, lines 3-15). The solid substrate may exist in any form, including, but not limited to reaction vessels, microtiter plates, membranes, and so on (column 2, lines 48-55). Okrongly further teaches that proteins, particulary biologically active proteins, and peptides, may be substituted into the polystyrene material.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to covalently bond antimicrobial peptides to the LbL polyionic bi-layer, since covalent attachment is well known to be resistant to washing, which is common in contact lens use.

3) Claims 2 and 3 are rejected under 35 USC 103(a) as being unpatentable over Winterton et al., and Sakuma et al., as applied to claim 1, and in further view of Diaz-Achirica et al.

Winterton and Sakuma, taught above, do not teach cecropin A melitin hybrid.

Diaz-Achirica et al. teach that cecropin A melitin hybrid peptides have been proven to be useful potent antibacterial peptides with broader specificity against

pathogens, while avoiding toxic side effects on eukaryotic cell types (see pages 2-3, results, and bridging paragraph 1.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use cecropin A melitin hybrid as the antimicrobial peptide of Winterton, since it is a potent antibacterial peptides with a broad specificity against pathogens, and avoids toxic side effects on eukaryotic cell types.

4) Claims 2, 4, 5, 16 and 17 are rejected under 35 USC 103(a) as being unpatentable over Winterton et al., and Sakuma et al., as applied to claim 1, and in further view of Diaz-Achirica et al.

Winterton teach where polyanionic material includes poly(allylamene hydrochloride) (PAH), (see pg. 5, [0063] and [0064], and plolycationic material, such as polyacrylic acid (PAA) (see pg.6, [0070] and [0072]), as per claims 4 and 5.

Diaz-Achirica et al. teach an antimicrobial peptide of claims 16 and 17, i.e. cecropin melatine hybrid peptides. (See Table 1 at pg. 261.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use the cecropin A melitin hybrid peptide as the antimicrobial peptide of Winterton, since it is a potent antibacterial peptides with a broad specificity against pathogens, and avoids toxic side effects on eukaryotic cell types.

(10) Response to Argument

Appellant argues that polystyrene of Okrongly does not satisfy the requirement of a first and second polyionic material as per claim 1. However, applicant is making a "piecemeal" analysis of the individual references, without addressing what is taught by their combined teachings. The Winterton reference teaches the first and second polyionic material as per claim 1. Okrongly was not used to meet this limitation of the claims. Rather, it teaches that peptides not covalently bound to a substrate are subject to being washed away. It would have been obvious to covalently bind the peptides of Diaz-Achirica to prevent them from being washed away through normal use of the contact lens.

Appellant argues that a *prima facie* case of obviousness has not been established, since the combination of the references dot not disclose or suggest all of the elements of the invention. Specifically, Appellant disagrees that the tertiary reference, Okrongly, provides motivation for the covalent bonding of one or more antimicrobial peptides of the peptide layer to the LbL coating through the reactive sites. However, Okrongly provides motivation insofar as it teaches covalent bonding of peptides to substrates, and that when the peptides are not covalently bound they are subject to being washed away. (See Okrongly at col. 5, lines 44-49.) The Examiner concluded that since contact lenses are subject to washing, it would have been obvious to covalently bind the peptides to the LbL layer. Furthermore, since the peptides are antimicrobial, it would have been obvious to secure them to the LbL coating in order to ensure their functionality in conjunction with the contact lens and its use.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Walter E. Webb

/Walter E Webb/

Examiner, Art Unit 1612

Conferees:

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Supervisory Patent Examiner
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